



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

5899 '02 JAN 23 P1:31

JAN 18 2002

Marianne Robb
Manager, Regulatory Affairs
Mallinckrodt Inc.
675 McDonnell Boulevard
St. Louis, MO 63134

Re: Docket No. 01P-0252/CP1

Dear Ms. Robb:

Pursuant to 21 CFR 10.30 (e)(2), this letter informs you that we are still considering the issues raised in your citizen petition requesting that the Food and Drug Administration determine whether dextroamphetamine sulfate tablets, 15 milligrams were withdrawn from sale for reasons of safety or effectiveness.

We expect to conclude our evaluation shortly and will respond to your petition once that process is completed.

Sincerely yours,

for Janet Woodcock
Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

OIP-0252

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